HFD-613

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-516/S-003

DEC 18 1998

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McNeil Consumer Healthcare
Attention: Willie D. Pagsuyuin
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Mr. Pagsuyuin:

Please refer to your supplemental new drug application dated December 1, 1997, received December 2, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (ibuprofen suspension), 100 mg/5mL.

Please also refer to the agency's approvable letter dated June 2, 1998. We acknowledge receipt of your resubmission dated June 19, 1998, received June 22, 1998.

The User Fee goal date for this supplemental new drug application is December 22, 1998.

This supplemental new drug application provides for three additional flavors (berry. grape, and bubble gum) for this product. The supplemental new drug application also provides for revised labeling.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling dated June 19, 1998. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-516/S-003." Approval of this submission by FDA is not required before the labeling is used.

As agreed in your letter dated December 2, 1998, the following revisions in the product labeling will be made at the time of the next printing or withing 180 days of receipt of this approval letter,

whichever comes first:

1. The header “Important” should be deleted. The phrase “Do not exceed recommended dose...” should be revised to read “Do not take more than directed.” This should be placed under the “Directions” section as the first bullet. The second sentence following “Do not exceed recommended dose” should be deleted.

2. The storage statement should be modified to read “Store between 20° - 25°C (68° - 77°F).)"

Furthermore, as agreed in your letter dated December 2, 1998, the “Aspirin Sensitive Children” statement should be replaced with the “Allergy alert” statement required by the Agency’s letter of September 15, 1998. This labeling revision should be implemented within the time frame outlined in that letter.

We also request that you consider reformatting the labeling as outlined in the February 27. 1997 FEDERAL REGISTER notice “Over-the Counter Human Drugs; Proposed Labeling Requirements” (62 FR 9024). Note, however, that the proposed labeling requirements and the draft prototype label are subject to change pending finalization of this rule.

Should additional information relating to the safety and effectiveness of the drug become available, further revision of the labeling may be required.

This approval affects only those changes specifically submitted in this supplemental new drug application. Other changes that may have been approved or are pending evaluation are not affected.

Please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Over-the-Counter Drug Products and two copies of both the promotional material and the labeling directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, we

request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this application, please contact Kerry Rothschild, Project Manager, at (30 1)827-2284.

Sincerely yours,

12/15/98
Debra L. Bowen, M.D.
Acting Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research